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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,894	01/30/2004	Kobi Iki	00167-491001/02-31-0464	4190

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EXAMINER	
TOY, ALEX B	
ART UNIT	**PAPER NUMBER**
3739	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,894	IKI ET AL.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *3,5-7,9,10,13-16,25-30,36,39 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,8,11,12,17-24,31-35,37,38,40,41 and 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 November 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to the telephone interview held on November 8, 2006 and applicant's subsequent amendment filed on November 16, 2006. The search has been updated in response to the issues raised in the interview and the corresponding amended claims as filed on November 16, 2006. The objection to the drawings is withdrawn. All previous prior art rejections are withdrawn.

Election/Restrictions

Based on applicant's disclosure that claims 13 and 14 correspond to Fig. 19, these claims are withdrawn from further consideration, since Fig. 19 corresponds to non-elected Species V.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims specify: a shaft, a flexible portion, and a head coupled to the shaft through the flexible portion and pivotably coupled to the flexible portion, the head including a non-conductive surface and an electrically conductive surface, wherein the flexible portion is configured to bias the non-conductive surface and the electrically conductive surface towards a tissue surface.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 17 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims specify: a shaft, a flexible portion, and a head coupled to the shaft through the flexible portion and pivotably coupled to the flexible portion, the head including a non-conductive surface and an electrically conductive surface, wherein the flexible portion is configured to bias the non-conductive surface and the electrically conductive surface towards a tissue surface. Furthermore, it

would be obvious, if not inherent, for the non-conductive surface of 10/766894 to be adjacent at least a portion of the electrically conductive portion, since the non-conductive portion limits penetration of the electrically conductive surface into the tissue surface.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 18 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 12 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims specify: a shaft, a flexible portion, and a head coupled to the shaft through the flexible portion, the head being pivotably coupled to the flexible portion, the head including a substantially planar tissue contact surface including a non-conductive portion and an electrically conductive portion. In addition, it would be obvious and require only routine skill in the art to make a flexible portion to be resiliently flexible since such materials are well-known and widely used in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 43 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably

distinct from each other because both claims specify: a shaft, a resiliently flexible portion, and a head coupled to the shaft through the resiliently flexible portion, the head being pivotably coupled to the resiliently flexible portion, the head including a substantially planar tissue contact surface including a non-conductive portion and an electrically conductive portion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 4, 8, 11-12, 17-24, 31-35, 37-38, 40-41, and 43-46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 12 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the more specific claims of 10/766894 encompass the broader claims in 10/999230. In addition, the "resiliently flexible portion" and "non-conductive surface" of 10/999230 are elements that are obvious and well-known to one of ordinary skill in the art. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 8 ,11-12, 17, 19-23, 32, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox (U.S. Pat. No. 5,919,191) in view of Irion (U.S. Pat. No. 6,251,108 B1).

Regarding claim 1, Lennox discloses an electrosurgical instrument comprising:

a shaft 20 (Figs. 1 and 4);

a flexible portion 46 (col. 5, ln. 61-63, col. 7, ln. 12-18, and Figs. 1 and 5-7); and

a head 14 coupled to the shaft 20 through the flexible portion 46 and pivotably coupled to the flexible portion (col. 11, ln. 13-16 and Fig. 8), the head including an electrically conductive surface (col. 5, ln. 50-60),

wherein the flexible portion 46 is configured to passively bias the electrically conductive surface towards a tissue surface (Figs. 5-7).

The claim differs from Lennox in calling for the head to include a non-conductive surface. Irion, however, teaches an analogous electrosurgical rolling head electrode 1 that includes an electrically conductive surface 11 and a non-conductive surface 12 in order to adjust a defined distribution of current density (col. 1, ln. 53 – col. 2, ln. 11 and Fig. 1b). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a non-conductive surface on the head of Lennox in view of the teaching of Irion in order to adjust a defined distribution of current density.

Regarding claim 4, Lennox further discloses that the flexible portion comprises a spring (col. 8, ln. 1-12 and Fig. 9).

Regarding claim 8, Lennox further discloses that the flexible portion is configured to flex in at least a direction and the head is configured to pivot about an axis substantially perpendicular to the direction (col. 11, ln. 13-16 and Figs. 8-9).

Regarding claim 11, Lennox further discloses that the head 14 includes a slot about which the head is configured to pivot (col. 11, ln. 13-16 and Figs. 1 and 8).

Regarding claim 12, Lennox further discloses that the slot is a transverse slot pivotably receiving the flexible portion (col. 11, ln. 13-16 and Figs. 1 and 8).

Regarding claim 17, Irion further discloses that the non-conductive surface 12 is arranged relative to the electrically conductive surface 11 to limit penetration of the electrically conductive surface into the tissue surface (col. 3, ln. 34-55 and Figs. 1a-b).

Regarding claim 19, Irion further discloses that the non-conductive surface is substantially flush with the electrically conductive surface (col. 3, ln. 34-55 and Figs. 1a-b).

Regarding claims 20 and 21, Irion discloses that it is well-known in the art to make an electrically conductive surface either flush with or project from a surface (col. 1, ln. 8-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the electrically conductive surface of Lennox either flush with or project from a non-conductive surface in view of the teaching of Irion since these constructions are well-known in the art, and it would have required only routine skill in the art. In addition, applicant has not disclosed any criticality or unexpected result associated with these limitations.

Regarding claim 22, Irion further discloses that the electrically conductive surface 11 has a first surface area, the non-conductive surface 12 has a second surface area, and the first surface area is smaller than the second surface area (col. 2, ln. 30-35 and Fig. 1b).

Regarding claim 23, Lennox further discloses that the head 14 comprises an electrode and the electrode includes the electrically conductive surface (col. 5, ln. 50-60).

Regarding claim 32, Lennox further discloses a sheath 28, 101 coupled to the shaft and moveable to at least partially cover the flexible portion and the head (col. 6, ln. 11-15 and Figs. 1a and 12).

Regarding claim 46, see the preceding rejection of claim 1.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox ('191) in view of Irion (U.S. Pat. No. 6,251,108 B1) and further in view of Rosar (U.S. Pat. No. 5,300,068).

Regarding claim 2, the claim differs from Lennox in calling for the flexible portion to comprise a nitinol wire. Lennox discloses that coagulating electrode head 14 has wire leads to connect the electrode to power source 21 (col. 6, ln. 4-6 and Fig. 1). These wire leads must be inherently flexible since they pass through the flexible portion 46 (Figs. 2 and 5-7). Rosar teaches an electrosurgical instrument, wherein a flexible wire lead 302 comprises nitinol (col. 9, ln. 54-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the wire leads of Lennox (and therefore, the flexible portion) comprise nitinol in view of the teaching of Rosar as an obvious material that is well-known in the art for making flexible wire leads.

Claims 18, 31, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox (U.S. Pat. No. 5,919,191) in view of Irion (U.S. Pat. No. 6,251,108 B1) and further in view of Grossi (U.S. Pat. No. 5,582,610).

Regarding claim 18, Lennox discloses that a non-rolling sled electrode may be used instead of a roller electrode for coagulation (col. 11, ln. 11-12). Lennox further discloses that the coagulating electrode can have different shapes to vary the coagulation pattern (col. 12, ln. 29-32). The claim differs from Lennox in calling for the non-conductive surface to be substantially planar. Grossi, however, teaches that it is obvious to make a sliding electrode surface substantially planar (Figs. 5 and 6a-b). In

addition, Irion teaches that his electrode with conductive and non-conductive surfaces can be in the shape of a plate (col. 2, ln. 40-44). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sliding electrode with conductive and non-conductive surfaces of Lennox in view of Irion have a substantially planar surface in view of the teaching of Grossi as an obvious shape for a sliding electrode that is known in the art.

Regarding claim 31, see the preceding rejection of claim 18. In addition, it would have required only routine skill in the art to make the trapezoidal head shape taught by Grossi to be parallelepiped since applicant has not disclosed any criticality or unexpected result associated with this specific shape.

Also, it would have been an obvious matter of design choice to make the head of Lennox of whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Regarding claim 43, see the rejections of claims 18 and 40.

Regarding claim 44, see the rejection of claim 43 and Fig. 1b of Irion.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox (U.S. Pat. No. 5,919,191) in view of Irion (U.S. Pat. No. 6,251,108 B1) and further in view of Nardella (U.S. Pat. No. 5,925,040).

Regarding claim 24, the claim differs from Lennox in view of Irion in calling for the electrode to have a T-shape. Nardella, however, teaches an analogous electrode roller

with conductive 194 and non-conductive 198 surfaces (Fig. 9). Nardella further teaches that the shape of the conductive portions 194 can be varied to in size and shape to increase the conductive surface area of the electrode (col. 8, ln. 3-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the electrodes 11 of Lennox in view of Irion to have a T-shape in view of the teaching of Nardella in order to increase the conductive surface area of the electrode. Further, since applicant has not disclosed any criticality or unexpected result associated with this shape, the examiner maintains that it would have required only routine skill in the art to select a T-shape for the electrode.

Also, it would have been an obvious matter of design choice to make the electrodes 11 of Lennox in view of Irion of whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Claims 33-35, 37-38, 40-41, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox (U.S. Pat. No. 5,919,191) in view of Grossi (U.S. Pat. No. 5,582,610).

Regarding claim 33, Lennox discloses a method of performing electrosurgery comprising:

positioning an electrically conductive surface of a head 14 of an instrument adjacent to a tissue surface, the head being pivotable relative to a shaft 20 of the instrument (col. 5, ln. 61-63, col. 7, ln. 12-18, and Figs. 1 and 5-7); and

moving the shaft relative to the tissue surface with the head pivoting such that the electrically conductive surface is oriented substantially parallel to the tissue surface (Figs. 5-10).

Lennox also discloses that a non-rolling sled electrode may be used instead of a roller electrode for coagulation (col. 11, ln. 11-12). Lennox further discloses that the coagulating electrode can have different shapes to vary the coagulation pattern (col. 12, ln. 29-32). The claim differs from Lennox in calling for the head to have a substantially planar tissue contact surface. Grossi, however, teaches that it is obvious to make a sliding electrode surface substantially planar (Figs. 5 and 6a-b). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sliding electrode of Lennox have a substantially planar surface in view of the teaching of Grossi as an obvious shape for a sliding electrode that is known in the art.

Regarding claim 34, Lennox further discloses the step of biasing the electrically conductive surface towards the tissue using a flexible portion 46 of the instrument (col. 5, ln. 61-63, col. 7, ln. 12-18, and Figs. 1 and 5-7).

Regarding claim 35, 37, and 38, see the preceding rejection of claim 33.

Regarding claims 40, 41, and 45, see the preceding rejections of claims 33 and 34 and Figs. 5-7 of Lennox.

Response to Arguments

Applicant's arguments with respect to the examined claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT AT
1/24/07

MICHAEL PEFFLEY
PRIMARY EXAMINER